propharma

case study

Program and Project Management: Effectively Deliver a QMS Optimization Program

With ProPharma's expertise, the pharma company was able to effectively overhaul and optimize their quality management system.

Several pharmaceutical companies experience periods of change in which they undergo mergers, divestitures, partnerships, or expansions into new therapeutic or treatment modalities.

As such, their Quality Management Systems (QMS) see commensurate evolutions in which new processes are created or existing processes are optimized to address these changes. The QMS also becomes impacted by the continued cycle of new regulations, audits, and inspections further introducing new documentation and revisions, creating added complexity.

> “Given the challenging schedules and competing priorities of our clients, they have minimal time to proactively address optimization of their QMS. Their time is typically spent firefighting that day’s issue and, as needed, addressing prioritized deficiencies or reacting to the release of updated or new regulation.

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challenge

A global, pharmaceutical company had undergone several restructurings through multiple acquisitions and other company events.

The result was a disjunctive QMS that did not effectively cascade from the highest levels of the organization to the lowest levels or across its integration points. Documentation types were not consistent across the functions or the sites. Everyone spoke with a different lexicon regarding core QMS concepts. Within a single quality system, some QMS content was duplicative, making it difficult to determine which suite of processes and documents should be followed. In other situations, some documents were unwieldy, very long, and very difficult to follow, due to the continued addition of content, post inspection or release of new/updated regulation.

Though these were recognized drivers to enhance the QMS, nothing significant was proactively done to improve the current state. The staff had competing priorities directing how to spend their time. A major organizational event would finally catalyze the activity to overhaul the enterprise quality system to better align with the new corporate structure.

This would allow the company to merge the separate, duplicative, function-specific quality systems into a more efficient, logical, consolidated, effective QMS. This would also minimize any potential compliance issues to regulations and improve operational effectiveness of the functions.

solution

ProPharma was engaged to provide their Project Management expertise to drive this complex program, but also leverage their Quality expertise in implementation of each of the workstreams.

We built and launched a program management office to structure and oversee the effort – objectives, scope, timing, key roles/responsibilities, workstreams (>15), and ongoing governance meetings.

The team consisted of a program manager, team leads for each workstream, and a suite of cross-functional experts driving and supporting each of those workstreams.

The team cataloged all global in-scope current state documentation.

To drive the project work and ensure consistency for the future state, the team designed the Policy Optimization approach and new Quality System Framework, developed new QMS policy, process, and procedure templates, and developed and executed a trace matrix approach to map policy elements to regulatory requirements.

During implementation, the team oversaw and drove assessment, obsolescence, and development of content for each QMS area and site-related documentation.

Finally, our team supported the build and launch of a new portal to better organize and retrieve QMS documentation.

results

With ProPharmas Project Management and QA expertise, we were able to **successfully execute a multi-year program in which >1000 new quality documents were created or revised and over >5000 legacy documents were obsoleted** due to redundancy or relevance.

Ongoing program meetings were conducted at the project level and at the senior sponsorship level to track progress and address issues, as necessary.

We identified an owner for each critical Quality Area (e.g., CAPA, Distribution, QRM) along with communities of practice to continue oversight of their QMS Area.

We utilized our Organizational Change Management expertise to create and launch an overarching governance group for the QA owners to ensure alignment across the QMS areas, post-project completion.

Finally, we improved audit/inspection outcomes by having a coherent picture and singular points of contact across the QMS for each area, irrespective of site.

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Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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